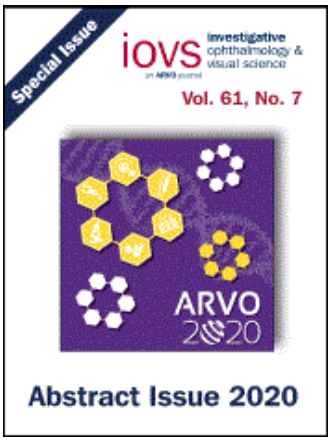

June 2020
Volume 61, Issue 7

‹ ISSUE ›

OPEN ACCESS

ARVO Annual Meeting Abstract | June 2020

Safety and Efficacy of Risuteganib in Intermediate Non-exudative Age-Related Macular Degeneration

Raj Maturi; Glenn J Jaffe; Justis P Ehlers; Peter K Kaiser; David S Boyer; Jeffrey S Heier; Julia A Kornfield; Baruch D Kuppermann; Hugo Quiroz-Mercado; Janine Aubel; Lisa Karageozian; Vicken H Karageozian; Melvin Sarayba

Author Affiliations & Notes

Investigative Ophthalmology & Visual Science June 2020, Vol.61, 1944. doi:

Abstract

Purpose: Risuteganib is a small synthetic peptide that regulates select

efficacy of risuteganib for the treatment of dry AMD.

Methods : Randomized, double-masked, placebo-controlled Phase 2 study in eyes with intermediate dry AMD presenting with best-corrected visual acuity (BCVA) between 20/40-20/200 was conducted across multiple centers in the United States. Patients were randomized to receive either intravitreal 1.0mg risuteganib or sham injection at baseline. At week 16, patients in the risuteganib group received a second dose and the sham group crossed over and receive a single dose of 1.0mg risuteganib. The primary endpoint was the percentage of population with ≥ 8 letters BCVA gain from baseline to week 28 in 1.0mg risuteganib vs baseline to week 12 for sham.

Results : Forty-five patients were enrolled in the study. At baseline, mean patient age was 78.8 and 75.9 years and mean baseline BCVA was 67.1 and 64.4 letters in the sham and risuteganib groups, respectively. The primary endpoint was met; 48% of patients in the risuteganib group at week 28 and 7% of patients in the sham group at week 12 gained > 8 letters from baseline (p=0.013). Of the risuteganib treated patients, 20% gained > 15 letters at week 28; no patients in the sham group at week 12 had this gain. On a post-hoc masked analysis by 2 independent reading centers, greater outer retinal and photoreceptor thickness and volume and smaller ellipsoid zone defect area in the central 1 mm zone at baseline were associated with increased BCVA response to risuteganib. Risuteganib demonstrated a good safety profile in this study.

Conclusions : Risuteganib showed significant benefit over sham in patients with dry AMD with respect to proportion of patients gaining > 8 letters of BCVA from baseline. Furthermore, post hoc analysis provides preliminary insights into baseline anatomic features that may help to determine likelihood of BCVA response to risuteganib. These findings will be confirmed in an upcoming larger trial.

This is a 2020 ARVO Annual Meeting abstract.